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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/920,871	08/02/2001	Robert L. Rykhus JR.	687-437	5424

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EXAMINER

THALER, MICHAEL H

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 02/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/920,871

Applicant(s)

RYKHUS ET AL.

Examiner

Michael Thaler

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16, 18-23 and 25-57 is/are pending in the application.
- 4a) Of the above claim(s) 26-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16, 18-23, 25 and 50-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Claims 26-49 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 8.

Claims 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hogan (6,569,191) in view of Stack (WO 91/17789). Hogan discloses a tubular sheath 21 and a walled surface comprised of polydioxanone (col. 2, line 58), the cylindrical sleeve having a limited in vivo lifetime (since it is bioabsorbable) which is controllable as indicated in col. 3, lines 20-23. Further, the in vivo lifetime is inherently "controllable" as claimed since it is controlled or determined at the time of manufacture by factors such as the size of the sleeve, the specific choice of bioabsorbable material, whether or not it is exposed to gamma radiation (and how much), noting that the Hogan stent is inherently capable of being exposed to gamma radiation. Hogan fails to disclose the stent as being annealed. However, Stack teaches that the bioabsorbable filaments of a self-expanding stent should be annealed in order to heat set them and thus insure that they will return to a helical form if distorted (page 26, lines 16-18). It would have been obvious to anneal the Hogan filaments so that the Hogan stent too would have this advantage. As to the term

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"fenestrated" walled surface, the openings between the threads of the Hogan stent are fenestrations, making the wall "fenestrated", as broadly claimed.

Claims 1-3, 8-11, 16, 18-23, 50, 51 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hogan (6,569,191) in view of Stack (WO 91/17789) and Cotterman et al. (2002/0153511). Hogan discloses a bioabsorbable self-expanding stent (col. 5, lines 50-66) comprising a cylindrical sleeve (e.g. 21) including a latticed network formed from a plurality of monofilaments 22, 26 braided in an alternating braid pattern (col. 5, lines 49-50) which comprise at least one biocompatible polymer (col. 7, lines 45-50), said cylindrical sleeve having a limited in vivo lifetime (since it is bioabsorbable) which is controllable as indicated in col. 3, lines 20-23. Hogan fails to disclose the stent as being annealed. However, Stack teaches that the bioabsorbable filaments of a self-expanding stent should be annealed in order to heat set them and thus insure that they will return to a helical form if distorted (page 26, lines 16-18). It would have been obvious to anneal the Hogan filaments so that the Hogan stent too would have this advantage. Hogan fails to disclose the stent as being gamma-irradiated. However, Cotterman et al. teach that a stent ([0043]) should be irradiated with gamma irradiation in the amount of 39 kGy in

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order to sterilize it effectively ([0098])). It would have been obvious to irradiate the Hogan stent with this amount of gamma irradiation so that it too would be sterilized. As to claims 20-23, Hogan fails to disclose the specific diameter claimed. However, it was well known in this art to size stents as with the specific diameter claimed so that it fits a correspondingly sized blood vessel. It would have been obvious to size the Hogan stent as claimed so that it would have this advantage. The above well known in the art statements are taken to be admitted prior art because applicant failed to traverse the examiner's assertions (M.P.E.P. 2144.03). As to claim 57, Hogan discloses poly-L-lactide in col. 2, line 55.

Claims 4 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hogan (6,569,191) in view of Stack (WO 91/17789) and Cotterman et al. (2002/0153511) as applied to claims 1 and 11 above, and further in view of Amstrup (5,476,508). Hogan fails to disclose a single strand shift in the braid. However, Amstrup teaches that braiding in a stent should include a single strand shift (at 12) in order to interlock the weave and apparently guarantee a stable crossing region which can accept large restoring forces (col. 4, lines 7-21). It would have been obvious to include a single strand shift in the Hogan braid so that it too would have this advantage.

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Claims 5-7 and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hogan (6,569,191) in view of Stack (WO 91/17789) and Cotterman et al. (2002/0153511) as applied to claims 1 and 9 above, and further in view of Thompson et al. (5,957,974). Hogan fails to disclose the claimed braid angle. However, Thompson et al. teach that the braid angle for a self-expanding stent should be 60-150 and preferably 90-100 degrees (col. 7, lines 21-22) apparently in order to optimize the amount of shortening (col. 7, lines 24-35). It would have been obvious to use this braid angle in the Hogan braid so that it too would have this advantage.

Claim 56 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hogan (6,569,191) in view of Stack (WO 91/17789) and Cotterman et al. (2002/0153511) as applied to claim 1 above, and further in view of Turnlund et al. (5,629,077). Hogan fails to disclose an under-two-over-two braid pattern. However, Turnlund et al. teach that the braid pattern for a stent should be under-two-over-two (col. 5, lines 54-56) apparently in order to obtain the desired strength of the mesh (col. 6, lines 6-9). It would have been obvious to use this braid pattern in the Hogan stent so that it too would have this advantage.

Claims 52-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hogan (6,569,191) in view of Stack (WO 91/17789) and Cotterman et al. (2002/0153511) as applied to claim 1 above, and further in view of Shaolian et al. (6,261,316). Hogan fails to disclose the claimed expansion force of 4, 6, 8 or 10 N or more. However, Shaolian et al. teach, in col. 14, lines 14-31, that the expansion force for a stent prosthesis should be as high as 8 lbs. (about 285 N) apparently in order to adequately expand the stent. It would have been obvious to provide the claimed expansion force for the Hogan stent so that it too would have this advantage.

Applicant's arguments filed Jan. 10, 2005 have been fully considered but they are not persuasive. As to the term "fenestrated", the openings 60 formed between the strands and spaced throughout the walled surface 58 in applicant's invention (figure 3 and [0049]) are considered to be fenestrations. Similarly, the openings formed between the strands and spaced throughout the walled surface of the Hogan stent are considered to be fenestrations. Although the fenestrations of applicant's invention are formed by being molded or cut into a wall as indicated on page 15 of applicant's response, the specification does not indicate that the term "fenestrations" used in the claims are required to be so formed. Further, the claims do not

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even refer to the method of forming the fenestrations. The definition of the term "fenestration" is "an "opening in a structure". Certainly, the openings in the Hogan stent meet this definition. Although Cotterman lists a number of medical products ([0043]), the reference specifically mentions stents in this same paragraph. Claim 52 requires a force of "6N or more" (underlining added). The Shaolian force of 71 N to 285 N (as calculated on page 19 of the response) meets this limitation.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael

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Thaler whose telephone number is (571)272-4704. The examiner can normally be reached Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571)272-4963. The fax phone number for the organization where this application or proceeding is assigned is (703)872-9306.

mht
2/8/05



MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3731